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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,420	10/25/2001	Sidney N. Wolfe	PP16022.004	2430

7590 11/08/2004

Chiron Corporation  
Intellectual Property Department  
P.O. Box 8097  
Emeryville, CA 94662-8097

EXAMINER

ANDRES, JANET L

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 11/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/035,420

**Applicant(s)**

WOLFE ET AL.

**Examiner**

Janet L. Andres

**Art Unit**

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 5-9, 13-17 and 19-49 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 5-9, 13-17 and 19-49 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **RESPONSE TO AMENDMENT**

1. Applicant's amendment filed 13 September 2004 is acknowledged. Claims 5-9, 13-17, and 19-49 are pending and under examination in this office action. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

### ***Claim Rejections/Objections Withdrawn***

2. The objection to the specification as containing a blank space is withdrawn in response to Applicant's amendment correcting the priority data.

3. The rejection of claims 1, 2, 4-18, and 20-35 under 35 U.S.C. 102(b) as anticipated by the '485 patent is withdrawn in response to Applicant's cancellation of claims 1, 2, 4, 10-12, and 18 and amendment to claims 5, 13, and 20.

4. The rejection of claims 3 and 19 under 35 U.S.C. 103(a) as unpatentable over the '485 patent in view of the '746 patent is withdrawn in response to Applicant's cancellation of claim 3 and amendment to claim 19.

### ***New Grounds of Rejection***

5. Claims 5-9, 13-17, 19-44, and 46-49 are newly rejected under 35 U.S.C. 103(a) as unpatentable over the '485 patent in view of U.S. patent 5,004,605. Claims 5-9, 13-17, and 19-49

Art Unit: 1646

are also rejected under 35 U.S.C. 103(a) as unpatentable over the '485 patent in view of the '605 patent and further in view of The Merck Index, 1989.

Applicant has amended all of the claims to require that the composition have a pH range of 3-5 and a buffer of glycine, aspartic acid, or succinate. The '485 patent teaches as set forth in the previous office action but fails to teach either the claimed pH range or succinate or aspartic acid buffers. The '605 patent teaches that beta interferon can be stored at a pH of 2-4 (column 4, lines 39-50, column 7, lines 58-69). The '605 patent additionally teaches that glycine can be used as a buffer for this purpose (column 9, lines 13-20). It would be obvious to one of ordinary skill in the art to combine the teachings of the '485 patent with those of the '605 patent to store the compositions of the '485 patent at a pH overlapping that taught by Applicant using glycine as a buffer, because the '605 patent teaches that interferon  $\beta$  can be stored in this fashion. Neither patent teaches succinate or aspartic acid as a buffer. However, the Merck Index, p. 132, teaches that aspartic acid is a weak acid with a pKa useful in this range. Thus it would be obvious to one of ordinary skill in the art to substitute aspartic acid for glycine, because the artisan of ordinary skill would recognize, based on the teachings of the Merck Index, that it would be equally effective.

With respect to the previous rejection of the claims under 35 U.S.C. 103(a), Applicant argues that the '485 patent does not teach the claimed pH range. Applicant argues that the '485 patent discloses a monomeric form only before oxidation and refolding. With respect to the rejection of claim 19 under 35 U.S.C. 103(a), Applicant argues that the '485 patent does not teach the instant pH ranges, and further teaches away from the instant ranges. Applicant additionally argues that

Art Unit: 1646

the '746 patent teaches that higher doses are preferred. Applicant additionally argues that neither patent teaches glycine, aspartic acid, or succinate buffers.

Applicant's arguments have been fully considered but have not been found to be persuasive. As stated above, the '485 patent in fact teaches that glycine may be used. In addition, the '485 patent stress the maintenance of activity on oxidation and refolding (column 12, lines 11-24); Applicant has provided no reasoning to indicate that the methods provided by the '485 patent would result in destruction of the desired monomeric form. While the '485 patent, as well as the '746 patent, cited in the previous rejection, teach higher pH ranges, these teachings are with respect to ease of administration, not the storage stability taught by the newly cited '605 patent ('485 patent as cited above and column 8, lines 43-47, of the '746 patent). Proteins in fact are often stored at acidic pH for purposes of stabilization, as was done in the '605 patent. Thus it would be *prima facie* obvious to prepare active interferon  $\beta$  at a pH optimal for storage.

NO CLAIM IS ALLOWED.

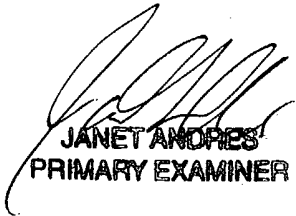
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Andres whose telephone number is 571-272-0867. The examiner can normally be reached on Monday, Tuesday, Thursday, Friday, 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1646

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Janet L. Andres, Ph.D.  
5 November 2004



**JANET ANDRES**  
**PRIMARY EXAMINER**